K013673

JAN 2 8 2002

Section 4 510(k) Safety and Effectiveness Summary

4.1 General Information

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Contact Person:	Kenneth D. Buroker TomoTherapy, Inc. 2228 Evergreen Rd. Middleton, WI 53562
Phone:	(608) 824-0995
Fax:	(608) 824-0996
Date:	November 3, 2001
Device Trade Name:	HI-ART System
Common Name:	Radiation Therapy System
Classification Name:	Medical Charged Particle Radiation Therapy System
Predicate Devices:	ADAC P3IMRT & Pinnacle 3 K002237 & K993923 Marconi AcQSim CT K923851 GE 3D Advantage Windows Fusion K983256 Marconi AcQSim Fusion K003437 Siemens Genesis IMRT K982502

4.2 Intended Use

The TomoTherapy HI-ART System is intended to be used as an integrated system for the planning and delivery of intensity modulated radiation therapy (IMRT) for the treatment of cancer. The HI-ART System provides precise delivery of radiation to tumors while minimizing the delivery of radiation to vital healthy tissue.

The HI-ART System's planning station is intended to be used by the physician/oncologist to prescribe a radiation therapy plan for a particular patient. The HI-ART System then calculates the treatment plan which the physician reviews and approves.

The HI-ART system's operator station and status console is then intended to be used by the therapist to select and implement the patient's treatment plan. The treatment process will begin by performing an MVCT scan (a CT using the onboard linear accelerator as the radiation source). This MVCT image will confirm that the patient's position is correct for the radiation therapy as well as assist in patient re-positioning when necessary. The MVCT image is not for diagnostic use.

When patient positioning is complete, the HI-ART System is then intended to be used by the therapist to treat the patient using the selected treatment plan. The HI-ART System delivers the radiation therapy treatment in accordance with the physician approved plan using IMRT techniques delivered in a helical tomographic pattern.

4.3 Description

The TomoTherapy HI-ART System is a radiation therapy system that integrates planning, dose calculation, megavoltage CT scanning, and helical radiation therapy treatment capabilities into a single comprehensive IMRT system.

The HI-ART System's planning station is used by the physician to prescribe and enter the radiation therapy plan. The patient's diagnostic CT image is imported via a DICOM protocol from another diagnostic CT device. The regions of interest, regions to avoid, and other prescribing information are entered in a manner that is similar to other commercially available planning systems.

The HI-ART System utilizes a 6 MV linear accelerator as the radiation source. The linear accelerator along with the primary collimator, multi-leaf collimator (MLC), xenon detector, various control devices and power supplies are mounted on a rotating gantry, much like a CT gantry. During treatment or imaging, the patient is positioned on the couch support, and the couch moves axially through the bore of the gantry, and the radiation is delivered in a helical pattern.

The primary collimator and the MLC control the beam dimensions during radiation delivery so that the range of collimated beam size can vary from 0 to 400 mm wide by 5 to 45 mm at the isocenter. The MLC is constructed of 64 tungsten leaves that open and close as determined by the radiation therapy plan. The intensity of the radiation beam is proportional to the length of time that a particular leaf is open. The opening and closing of various leaves as the radiation is delivered in this helical pattern allows for an IMRT plan to be delivered with precise control. The result is a highly conformal dose to the region of interest with low doses to surrounding healthy tissue.

Because the HI-ART System is operating in a helical mode similar to CT systems, it inherently has the ability to obtain a CT image. The system utilizes the linear accelerator to obtain a megavoltage (MVCT) scan of the region of interest prior to the delivery of radiation therapy. This MVCT image is then used in a non-diagnostic mode to ascertain that the patient is correctly positioned prior to treatment. The radiation dose to the patient from an MVCT scan is comparable to diagnostic CT or portal imaging.

4.4 Safety Considerations

The HI-ART System has several characteristics that promote its safety – no beam blocks are used that can fall off onto the patient; the rotating gantry is covered so that the patient cannot contact moving gantry parts; the linear accelerator operates in photon mode only

so inadvertent electron exposure is virtually eliminated; MVCT allows for reliable patient positioning.

Also, the HI-ART System consists of components similar to those already commercially marketed, including the 6 MV linear accelerator, rotating gantry, patient couch and CT imaging devices.

4.5 Standards Compliance

The HI-ART System is designed to comply with relevant sections of the IEC 60601-1 series safety standards.

4.6 Validation

The HI-ART System was extensively validated for system functionality, including planning, imaging, delivery, database management, DICOM communications, etc. Test tools utilized in this testing included IMRT phantoms, ion chambers and other test phantoms.

4.7 Conclusion

Validation and verification testing of the HI-ART System demonstrate the device is safe and effective for its intended use. The HI-ART System is substantially equivalent to other commercially marketed systems for the various capabilities of the HI-ART.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2002

Mr. Kenneth D. Buroker
Director, Regulatory Affairs & Quality
TomoTherapy, Inc.
2228 Evergreen Road
MIDDLETON WI 53562-4241

Re: K013673
Trade/Device Name: TomoTherapy HI-ART System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: November 3, 2001
Received: November 6, 2001

Dear Mr. Buroker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 3 Indications for Use Form

- 510(k) Number (if known) _____
- Device Name: **TomoTherapy HI-ART System**
- Indications for use:

The TomoTherapy HI-ART System is intended to be used as an integrated system for the planning and delivery of intensity modulated radiation therapy (IMRT) for the treatment of cancer. The HI-ART System provides precise delivery of radiation to tumors while minimizing the delivery of radiation to vital healthy tissue.

The HI-ART System's planning station is intended to be used by the physician/oncologist to prescribe a radiation therapy plan for a particular patient. The HI-ART System then calculates the treatment plan which the physician reviews and approves.

The HI-ART system's operator station and status console is then intended to be used by the therapist to select and implement the patient's treatment plan. The treatment process will begin by performing an MVCT scan (a CT using the onboard linear accelerator as the radiation source). This MVCT image will confirm that the patient's position is correct for the radiation therapy as well as assist in patient re-positioning when necessary. The MVCT image is not for diagnostic use.

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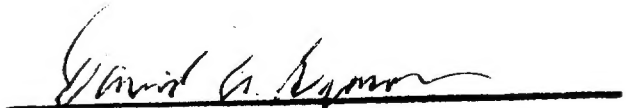
PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 810.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013673